

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION**

SIGMA-ALDRICH, INC., et al.,)
)
Plaintiffs,)
)
v.) No. 4:06-CV-754 CAS
)
OPEN BIOSYSTEMS, INC.,)
)
Defendant.)

MEMORANDUM AND ORDER

This matter is before the Court on defendant Open Biosystems, Inc.’s Motion to Dismiss for Lack of Standing. Plaintiffs oppose the motion and defendant has filed a reply.¹ Plaintiffs were granted leave to file a surreonse and defendant a surreply. For the following reasons the Court will deny the motion to dismiss.

Background.

Plaintiff Oxford BioMedica (UK) LTD. (“Oxford”) is a biopharmaceutical company that specializes in the development of novel gene-based therapeutics, with a focus on cancer (oncology) and neurological disorders (neurotherapy). The company was established in 1995 out of Oxford University, by Drs. Alan and Susan Kingsman, the co-inventors of the patents-in-suit and professors at Oxford University. Declaration of Peter Nolan (“Nolan Decl.”), ¶¶ 2-4.

Plaintiff Sigma-Aldrich, Inc. (“Sigma”) is a leading manufacturer of reagents and materials used in research, development and diagnostics. It manufactures a wide variety of chemical products at several plants, which it then sells to laboratories throughout the world for use in scientific research,

¹Defendant argues that plaintiffs’ Joint Opposition to Defendant’s Motion to Dismiss for Lack of Standing [Doc. 47] was untimely filed. To the extent the opposition was late, which the Court does not decide, leave to file out of time is hereby granted.

including biotechnology and pharmaceutical development. This includes genomic research, i.e., the study of genes and their function in disease and in therapy. Nolan Decl., ¶ 8.

Oxford owns a number of key patents, including the two patents-in-suit, that relate to the use of lentiviral vectors as reagents in genomic research, as well as for delivery of genetic material in targeted gene therapy applications.² Id., ¶¶ 2-5. On October 19, 2005, Oxford entered into a licensing agreement that purported to grant Sigma the exclusive rights to manufacture and distribute Licensed Products (as defined infra) for research purposes.³ Id., Ex. E (the “License Agreement”). The License Agreement covers numerous patents in the United States and elsewhere, including the patents-in-suit.

The complaint, which was initially filed by Sigma only and was not served on defendant, alleges that defendant is infringing these exclusive rights by manufacturing its own lentiviral vectors and selling them to researchers. Oxford joined the litigation as a co-plaintiff in an Amended Complaint filed on June 8, 2006. In the Amended Complaint, the plaintiffs contend that defendant is infringing in the same field to which Sigma holds the exclusive rights, causing a direct injury to both Sigma and Oxford. See Declaration of Elizabeth A. Richardson (“Richardson Decl.”).

The Amended Complaint alleges the infringement of two patents, U.S. Patent No. 6,924,123 (“the ‘123 patent”) and U.S. Patent No. 7,056,699 (“the ‘699 patent”). The patents at issue concern the use of vectors derived from lentiviruses that are used to deliver selected genetic material into

²A vector is a vehicle or agent which is designed to carry selected genetic material, in order to introduce the selected genetic material into a cell. Nolan Decl., ¶ 7.

³The use of the patented lentiviral vector in the medical field is distinct from its use in the research field. Administering a patented lentiviral vector to human patients for the purpose of gene therapy, e.g., as a vehicle to deliver a needed gene to a patient for gene therapy, is different from using the vector in a basic research laboratory to study gene function, or to search for drug candidates. See Declaration of Shaf Yousaf (“Yousaf Decl.”), ¶ 11.

particular cells. The lentiviral vectors are based on viruses, such as HIV, which have been modified to be used to deliver genetic material, such as RNA, to targeted cells.

Defendant is a corporation organized under the laws of Delaware and has its principal place of business in Alabama. Plaintiffs allege that defendant has manufactured, used, offered for sale and/or sold products that infringe on the ‘123 and ‘699 patents, and/or has actively induced or contributed to the infringement of the patents-in-suit.

In the instant motion, defendant asserts that plaintiff Sigma lacks standing to bring this action because it is a mere “bare licensee” under the patents. Defendant also asserts that the entire case must be dismissed because Sigma was the only plaintiff at the time the complaint was filed, and Sigma lacked standing to bring the action. Defendant asserts that the claims of plaintiff Oxford should be dismissed with prejudice because Oxford knowingly contemplated Sigma instituting an improper lawsuit without Oxford’s participation, and therefore is not an innocent bystander.

Legal Standard.

“Standing to sue is a threshold requirement in every federal action” and “must be present at the time the suit is brought.” Sicom Sys., Ltd. v. Agilent Techs., Inc., 427 F.3d 971, 975-76 (Fed. Cir. 2005). The burden to establish standing rests on Sigma. “It is well established . . . that before a federal court can consider the merits of a legal claim, the person seeking to invoke the jurisdiction of the court must establish the requisite standing to sue.” Whitmore v. Arkansas, 495 U.S. 149, 154 (1990). When a standing issue is raised by mean of a motion to dismiss, however, the court “must accept as true all material allegations of the complaint, and must construe the complaint in favor of the complaining party.” Warth v. Seldin, 422 U.S. 490, 501 (1975).

Discussion

I.

The Federal Circuit has addressed the issue of standing numerous times in patent cases, and has established the governing principles which control the issue.⁴ “The Patent Act provides that a ‘a patentee’ is entitled to bring a civil action ‘for infringement of his patent.’ 35 U.S.C. § 281. The term ‘patentee’ includes ‘not only the patentee to whom the patent was issued but also the successors in title to the patentee.’ Id., § 100(d).” Propat Int’l. Corp. v. Rpost, Inc., 473 F.3d 1187, 1189 (Fed. Cir. 2007) (internal punctuation omitted). “Those provisions of the Patent Act have been interpreted to require that a suit for infringement of patent rights ordinarily be brought by a party holding legal title to the patent.” Id. (citing Sicom Sys. Ltd., 427 F.3d at 976; Rite-Hite Corp. v. Kelley Co., Inc., 56 F.3d 1538, 1551 (Fed. Cir. 1995) (en banc); Abbott Labs. v. Diamedix Corp., 47 F.3d 1128, 1130 (Fed. Cir. 1995)).

“Even if the patentee does not transfer formal legal title, the patentee may effect a transfer of ownership for standing purposes if it conveys all substantial rights in the patent to the transferee. In that event, the transferee is treated as the patentee and has standing to sue in its own name.” Propat, 473 F.3d at 1189 (citing Speedplay, Inc. v. Bebop, Inc., 211 F.3d 1245, 1250 (Fed. Cir. 2000); Vaupel Textilmaschinen KG v. Meccanica Euro Italia SPA, 944 F.2d 870, 875 (Fed. Cir. 1991)).

“A party that is neither the legal owner of the patent nor the transferee of all substantial rights in the patent still has standing to sue for infringement if that party has a legally protected interest in the patent created by the Patent Act, so that it can be said to suffer legal injury from an act of

⁴Decisions of the Federal Circuit Court of Appeals are binding on federal district courts in substantive matters concerning patent law. See Broyhill Furniture Indus., Inc. v. Craftmaster Furniture Corp., 12 F.3d 1080, 1083 (Fed. Cir. 1993).

infringement.” Propat, 473 F.3d at 1193 (citing Intellectual Property Dev., Inc. v. TCI Cablevision of Cal., Inc., 248 F.3d 1333, 1345-46 (Fed. Cir. 2001)). “An exclusive licensee is considered to have such an interest. Unlike the patentee or the transferee of all substantial rights in the patent, however, an exclusive licensee ordinarily may not sue in its own name alone, but must join the patent owner in an action brought against an accused infringer.” Propat, *id.* (citing Independent Wireless Tel. Co. v. Radio Corp. of Am., 269 U.S. 459, 464, 468-69, 473-74 (1926); Waterman v. Mackenzie, 138 U.S. 252, 255 (1891); Textile Prods., Inc. v. Mead Corp., 134 F.3d 1481, 1484 (Fed. Cir. 1998); Abbott Labs., 47 F.3d at 1131).

“An exclusive licensee receives more substantial rights in a patent than a nonexclusive licensee, but receives fewer rights than an assignee of all substantial patent rights.” Intellectual Prop. Devel., 248 F.3d at 1345. “For example, an exclusive licensee could receive the exclusive right to practice an invention within a given limited territory.” *Id.* (citing Rite-Hite, 56 F.3d at 1552).

In contrast, “a bare licensee, i.e., a party with only a covenant from the patentee that it will not be sued for infringing the patent rights, lacks standing to sue third parties for infringement of the patent.” Propat, 473 F.3d at 1193. “Thus, an infringement action brought by a bare licensee must be dismissed. A bare licensee cannot cure its lack of standing by joining the patentee as a party.” *Id.* at 1193-94 (citing, *inter alia*, Intellectual Property Dev., 248 F.3d at 1348-49; Textile Prods., 134 F.3d at 1485; Abbott Labs., 47 F.3d at 1131)).

In Independent Wireless, the Supreme Court explained the rationale underlying the rule regarding suits by exclusive licensees and the requirement that the patent owner be joined as a plaintiff:

[T]he owner of a patent, who grants to another the exclusive right to make, use, or vend the invention, which does not constitute a statutory assignment, holds the title

to the patent in trust for such a licensee, to the extent that he must allow the use of his name as plaintiff in any action brought at the instance of the licensee in law or in equity to obtain damages for the injury to his exclusive right by an infringer, or to enjoin infringement of it.

269 U.S. at 469. “The patentee is brought into the suit for substantive reasons, namely, to protect its own interests in connection with the charged acts of infringement and ‘to enable to alleged infringer to respond in one action to all claims of infringement for his act.’” Ortho Pharm. Corp. v. Genetics Institute, Inc., 52 F.3d 1026, 1034-35 (Fed. Cir. 1995) (quoting Independent Wireless, 269 U.S. at 468).

The Federal Circuit “has characterized the rule in Independent Wireless as meaning that an exclusive licensee has a sufficient interest in the patent to have standing to sue under Article III of the Constitution.” Propat, 473 F.3d at 1193 (citations omitted). The “requirement that the exclusive licensee must normally join the patent owner in any suit on the patent is a ‘prudential’ requirement, not a constitutional requirement based on Article III limitations, and . . . an action brought by the exclusive licensee alone may be maintained as long as the licensee joins the patent owner in the course of the litigation.” Propat, 473 F.3d at 1193 (citing Intellectual Property Dev., 248 F.3d at 1348; Mentor H/S, Inc. v. Medical Device Alliance, Inc., 240 F.3d 1016, 1019 (Fed. Cir. 2001)).

II.

The parties do not dispute that Oxford is the assignee of the ‘123 and ‘699 patents, and accordingly Sigma is some form of licensee and not the patentee or an assignee. As a result, Sigma cannot proceed alone as plaintiff in this action. See Propat, 473 F.3d at 1193. The issue presented by defendant’s motion is whether Sigma has sufficient rights in the ‘123 and ‘699 patents to obtain standing when joined by Oxford, in other words whether Sigma is an exclusive licensee, or whether Sigma lacks standing at all because it is a bare licensee.

To resolve this issue, the Court must examine the License Agreement between Sigma and Oxford to determine what type of license was granted to Sigma. See Depuy Spine, Inc. v. Medtronic Sofamor Danek, Inc., 469 F.3d 1005, 1025 (Fed. Cir. 2006). To determine the nature of the license granted, the intent of the parties must be discerned, based on the terms of their agreement:

Determining whether a licensee is an exclusive licensee or a bare licensee is a question of ascertaining the intent of the parties to the license as manifested by the terms of their agreement and examining the substance of the grant. The use of the word “exclusive” is not controlling; what matters is the substance of the arrangement. Because patent rights are rights to “exclude others,” a licensee is an exclusive licensee only if the patentee has promised, expressly or impliedly, that “others shall be excluded from practicing the invention” within the field covered by the license. Put another way, an exclusive license is “a license to practice the invention accompanied by the patent owner’s promise that others shall be excluded from practicing it within the field of use wherein the licensee is given leave.”

Textile Prods., 134 F.3d at 1484 (internal citations omitted).

The License Agreement in this case provides that it shall be construed in accordance with New York law, without giving effect to New York’s conflict of laws principles or rules. See License Agreement, § 17.1. Under New York law, when the terms of a written contract are clear and unambiguous, it is the primary rule of construction of contracts that “the intent of the parties must be found within the four corners of the contract, giving a practical interpretation to the language employed and the parties’ reasonable expectations.” Pecker Iron Works of New York, Inc. v. Traveler’s Ins. Co., 736 N.Y.S.2d 103, 104 (N.Y. App. Div. 2002) (quoted case omitted), aff’d, 99 N.Y.2d 391 (N.Y. 2003).

Defendant contends that Sigma is a bare licensee and does not have standing, and that the lack of standing cannot be cured by the addition of Oxford as a party. Defendant supports its contention by asserting that (1) Sigma’s claimed “exclusive license” is subject to at least one pre-existing license on the patents-in-suit; (2) the non-exclusive license Sigma holds is for substantially less than all the

rights under the patents-in-suit; and (3) Sigma lacks substantial proprietary rights that are reserved to Oxford under the License Agreement, including that (a) Oxford retains the rights to develop, make and use the licensed technology, and to grant licenses to third parties (within the Licensed Field) upon Sigma's consent, which cannot be unreasonably withheld; (b) Oxford retains the first right to sue under the patents; and (c) Oxford is solely responsible for prosecution and maintenance of the patents and associated fees.

Upon review of the terms of the License Agreement, the Court concludes that the license grants Sigma exclusive rights within a defined field of use, and that under principles of standing as established by the Federal Circuit, Sigma had standing to file this action by itself and add Oxford as a co-plaintiff shortly thereafter.

A.

The License Agreement grants Sigma an “exclusive license” to manufacture products under the patents-in-suit (as well as other patents) and to sell within a defined field; specifically to sell patented lentiviral vectors to third-party researchers for in vivo or in vitro genetic research.⁵ This is confirmed by the language of the License Agreement and its practice.

Section 2.1(a) of the License Agreement grants the following license to Sigma:

Subject to the terms and conditions set forth herein, including without limitation, Section 2.3 below, Licensor hereby grants to Sigma, together with its Affiliates [companies owned and controlled by Sigma], a world-wide, royalty-bearing, exclusive license under the Licensed Patents to make, have made, sell, offer for sale, and import Licensed Products and Licensed Services for commercial use within the Licensed Field.

⁵The term “in vivo” can be an adjective or adverb and means “within a living organism.” American Heritage Dictionary (4th ed. 2000). The term “in vitro” can also be an adjective or adverb and means “in an artificial environment outside the living organism.” Id.

This license gives Sigma the right to make and sell the patented inventions within a defined field, but not the right to use the products (such as for conducting its own laboratory research). See 35 U.S.C. § 271(a) (stating that a patent gives the patentee the exclusive rights to “make,” “use,” “sell,” “offer to sell,” and “import” a patented invention within the United States). The scope of this license is consistent with Sigma’s status as a manufacturer and distributor. See Nolan Decl., ¶ 8.

Section 2.1(a) states that the exclusive license is for a defined “Licensed Field”:

“Licensed Field” means in vivo or in vitro research whose purpose includes, but is not limited to, elucidation of gene functions, including research to validate potential gene products and pathways for drug discovery and development. The Licensed Field goes not include any use of LentiVector technology to create transgenic birds for the purpose of producing useful or valuable proteins in the eggs of such transgenic birds, the use of LentiVector technology for the delivery of gene therapies, or the use of LentiVector technology for commercial production of therapeutic, diagnostic, or other commercial products not intended for research use where such products do not consist of or incorporate a lentiviral vector.

Nolan Decl., Ex. E (emphasis added). This section clarifies what falls inside the exclusive license, i.e., patented products used specifically for in vivo and in vitro research, and what falls outside, i.e., patented products used for therapeutic purposes or production of commercial products.

Section 2.1(a) further clarifies that the license is for certain “Licensed Products” and “Licensed Services” within the Licensed Field. These terms are defined in Article 1 of the License Agreement:

“Licensed Products” means any reagent or research tool consisting of or incorporating lentiviral vector(s), based on human immunodeficiency virus (HIV) and covered by one or more Valid Claims under the Licensed Patents in the Licensed Field and includes (for the avoidance of doubt) the use of the VSV-G envelope in Licensed Products.

“Licensed Services” shall mean services using Licensed Products for target identification and validation and the development of custom reagents and tools consisting of or incorporating HIV-based lentiviral technology and covered by one or more Valid Claims under the Licensed Patents in the Licensed Field.

Nolan Decl., Ex. E. These “Licensed Products” are the patented lentiviral vectors provided as commercial reagents; key tools that researchers use to conduct further research in genetics and gene therapy. Nolan Decl., ¶ 15.

The License Agreement therefore gives Sigma certain exclusive rights within a defined field, namely to be the exclusive manufacturer and distributor of Licensed Products (patented lentiviral vectors) in the Licensed Field (in vivo and in vitro genetic research).

The Federal Circuit has found co-plaintiff standing even where the exclusive rights are more limited than Sigma’s and not reduced to writing. In Weinar v. Rollform Inc., 744 F.2d 797, 807 (Fed. Cir. 1984), the Federal Circuit held that a distributor with an oral agreement to be the exclusive United States distributor of a patented product, but with no exclusive rights to make or use the product, was nevertheless an exclusive licensee with co-plaintiff standing. The court specifically rejected the defendant’s contention that the exclusive distributor was merely a “bare licensee” without standing. Id.; see also Inzer v. Frantz, Civ. No. 03-0552, 2003 U.S. Dist. Lexis 13899, **16-18 (N.D. Ill. Aug. 6, 2003) (holding that distributor had co-plaintiff standing through license that granted exclusive rights “for the limited purpose of manufacturing, distributing and selling” the patented products within a particular field); James v. Victor Co. of Japan, Civ. No. 98-862, 1998 U.S. Dist. Lexis 19854, *14 (D. Md. July 31, 1998) (holding that distributor had co-plaintiff standing through distribution agreement with “implicit promise of exclusivity”); Sanofi, S.A. v. Med-Tech Veterinarian Prods., Inc., No. 83-2198, 1983 U.S. Dist. Lexis 13684, **14-16 (D. Kan. Sept. 16, 1983) (holding that “limited exclusive licensee” had co-plaintiff standing through exclusive rights to distribute pharmaceutical product only in veterinary field); cf. Kalman v. Berlyn Corp., 914 F.2d 1473, 1481 (Fed. Cir. 1990) (citing Sanofi with approval).

In this case, Sigma has more exclusive rights than in Weinar, specifically to both make and sell the products in the Licensed Field, and these rights are clearly spelled out in the License Agreement. The License Agreement establishes Sigma as the exclusive manufacturer and distributor of certain patented products within a defined field of exclusivity, and forbids Oxford from granting other licenses in this field without Sigma's express consent.⁶ As in Intellectual Property Development, the License Agreement grants far more than a bare, nonexclusive license, and Sigma has co-plaintiff standing. See Intellectual Property Dev., 248 F.3d at 1342-46.

B.

Defendant also argues that Sigma cannot be an exclusive licensee because its rights are subject to certain reserved rights for preexisting licensees. Upon careful review of the record, the Court determines that the License Agreement is subject to only one nonexclusive prior license for the patents-in-suit, and that license has no conflict with Sigma's exclusive rights as a distributor.

Under Section 2.2 of the License Agreement, Sigma agrees to allow certain preexisting licensees to continue using the patented technology for their own "internal use":

2.2 Prior Licenses. Notwithstanding the exclusive character of the licenses granted to Sigma in this Agreement, Sigma recognizes and accepts the existence of particular prior licenses granted by Licensor listed on Schedule 2.2 hereof. Sigma acknowledges that the exclusivity of the license granted in Section 2.1 above is subject to such licenses, and further acknowledges that Licensor shall have the right to continue such existing licenses to existing licensees to use Licensed Products in the Licensed Field only for such existing licensee's internal use.

Nolan Decl, Ex. E (emphasis added). None of these prior licenses conflicts with Sigma's exclusive rights.

⁶The Court discusses Oxford's retained ability to grant additional licenses infra at § II.C., at 15-18.

As stated above, only one preexisting license concerns the two patents-in-suit. That license is only for making and using the patented products for in-house research, and is not for making and selling the patent products to third parties. The unredacted version of Schedule 2.2 of the License Agreement lists seven preexisting licenses. Nolan Decl., ¶¶ 20-22. Only one of the license agreements (for a leading biotechnology research company) grants any rights to practice the two patents-in-suit. The remaining six license agreements are for other patents included within the Sigma License Agreement but not relevant to this suit, such as foreign patents for companies conducting research outside of the United States. Id., ¶¶ 23-24; Richardson Decl., ¶¶ 4-11.

Moreover, each of the seven preexisting licensees is either an academic or a commercial research lab, not a manufacturer or distributor of patented lentiviral vector products. Nolan Decl., ¶ 24. Each preexisting agreement, including the single agreement which concerns the patents-in-suit, only grants a right to make and use the patented lentiviral vectors for the lab's "internal use," as confirmed by Section 2.2 of the Sigma License Agreement. In fact, each agreement expressly prohibits the licensee from selling any patented products to third parties. Nolan Decl., ¶ 24; Richardson Decl., ¶¶ 4-11. Because these companies can only manufacture these products for their internal research, not for sale, there is no conflict with Sigma's exclusive rights. Yousaf Decl., ¶ 6.

Further, the various preexisting nonexclusive licenses are not determinative of Sigma's status. The question is not whether Sigma must allow certain preexisting uses to continue, but instead whether Sigma has the rights to exclude anyone else from entering the exclusive field in the future:

The issue [of whether a license is exclusive] should be whether the patent owner is precluded after the date of the instrument from granting further licenses within the stated area given to the licensee. Thus, a license may still be exclusive even though the patent owner had previously granted nonexclusive licenses in the area. Similarly, reservation by the patent owner of the right to personally make, use or sell the

claimed invention does not preclude exclusivity. It would seem that the area of exclusivity may be in terms of geography, time or field-of-use.

⁸ Donald S. Chisum, Chisum on Patents, § 21.03[2][c], 21-486 to 488 (2002) (footnotes omitted).

As plaintiffs assert, obtaining an exclusive license subject to certain defined preexisting uses is comparable to purchasing real estate subject to an easement. The new owner knowingly acquires the property subject to certain reserved rights, but has the exclusive right going forward to exclude anyone else from using the property in the exclusive field of use.

Courts have recognized that a license may be exclusive even where preexisting nonexclusive licenses exist. In Abbott Laboratories, for example, the license was sufficiently exclusive to confer co-plaintiff standing even though the patentee “retained a limited right to make, use, and sell products embodying the patented inventions,” and the license was further “subject to the rights previously granted to [the patentee’s] other licenses.” Abbott Labs., 47 F.3d at 1129, 1131; see also Intellectual Property Dev., 248 F.3d at 1336 (license was exclusive and conferred co-plaintiff standing even though “subject to a [preexisting] nonexclusive license”).

In Hill Phoenix Inc. v. Systematic Refrigeration Inc., 117 F.Supp.2d 508 (E.D. Va. 2000), the district court stated:

What confers standing is the right to prevent others from using the patented technology. The Federal Circuit has never stated that the licensee must have the right to exclude all others. If a patentee grants a second license that is subject to a prior-existing, nonexclusive license, but otherwise provides the second licensee with the right to exclude all others except the prior licensee, then the subsequent licensee has proprietary rights sufficient to confer standing.

Id. at 512-13; see also Int'l Gamco, Inc. v. Multimedia Games, Inc., Civ. No. 04-1053-B, 2006 U.S. Dist. Lexis 88010, *14 (S.D. Cal. Dec. 4, 2006) (“Where a patentee has granted a second party an ‘exclusive license’ subject to a prior existing non-exclusive license with a first party, the second party

still has standing to sue.”); Loegering Mfg., Inc. v. Grouser Prods., Inc., 330 F.Supp.2d 1057, 1073 (D.N.D. 2004) (“Even when there are other nonexclusive licensees, a licensee with sufficient rights may join the patentee as a co-party.”). Here, the License Agreement is subject to only one nonexclusive prior license for the patents-in-suit, and that license has no conflict with Sigma’s exclusive rights as a distributor.

C.

Defendant also argues that the License Agreement is not exclusive because Oxford retained certain rights for itself under the patent, including the rights to grant further licenses. The terms of the License Agreement reveal, however, that Oxford retained no right to act as a distributor within the Licensed Field, and has no right to grant any additional licenses without Sigma’s written consent.

In Section 2.3 of the License Agreement, Oxford retained only limited rights for itself, specifically the rights to “develop, make and use” Licensed Products for “research purposes only.” Oxford did not retain any rights to “sell” Licensed Products to researchers. The License Agreement provides in pertinent part:

2.3 Retained Rights of Licensor. It is acknowledged and agreed by the Parties that the exclusive right to Sigma under Section 2.1 above is subject to the retained right in Licensor to develop, make and use Licensed Products in the Licensed Field for research purposes only; provided, it is further acknowledged and agreed by the Parties that, absent the prior written consent of Sigma, such consent not to be unreasonably withheld, no license will be granted by Licensor after the date hereof that includes the right to make, have made or sell Licensed Products in the Licensed Field or to offer Licensed Services in the Licensed Field. Any request for such Sigma consent shall be in writing and presented and evaluated through the [Joint Technology Committee] (defined below), and Sigma shall notify Licensor of its consent, or refusal to consent, within sixty (60) days of from the date of receipt of a written request by Licensor. By way of example, and not by way of limitation, it shall not be unreasonable for Sigma to withhold consent in connection with such a license where rights are granted to use, develop, make or have made any Licensed Product or derivative or variant thereof which are offered for commercial sale by Sigma and set forth on Schedule B hereto, or are under development for commercial sale by Sigma. Schedule B shall be

amended by Sigma from time to time to reflect its then current Licensed Product offerings.

Nolan Decl., Ex. E (emphases added). As discussed above, a limited reservation of rights by the patentee itself can be consistent with an exclusive license. See Abbott Labs., 47 F.3d at 1129, 1131 (license was exclusive even though patentee “retained a limited right to make, use, and sell products embodying the patented inventions”); Weinar, 744 F.2d at 807.

Under Section 2.3, Oxford did not retain any rights to “sell” patented lentiviral products within the Licensed Field. Those rights belong exclusively to Sigma. Oxford only retains the rights to make products for internal “research purposes only.” If any third-party researchers want to purchase the patented lentiviral vectors, they must purchase them from Sigma.

Oxford also cannot grant licenses to third parties that exceed its own rights. Oxford has already conveyed to Sigma the exclusive right to sell Licensed Products within the Licensed Field. Oxford cannot grant additional licenses for rights that it no longer owns. See Sanofi, 1983 U.S. Dist. Lexis 13684 at *17 (after granting exclusive license, patentee no longer retains rights to sell licensed product in the licensed field, and cannot grant additional licenses to third parties for those rights).

Oxford’s limited ability to grant further licenses is further constrained by the express terms of Section 2.3. Oxford cannot grant any more licenses in this field without “the prior written consent of Sigma.” Nolan Decl., Ex. E. This gives Sigma veto power over any further licenses in this field. If any research lab wants a license to make and use patented products for in-house research, it must obtain permission jointly from both Oxford and Sigma. As the parties noted in a contemporaneous

joint press release announcing their partnership, the License Agreement "gives Sigma-Aldrich the exclusive right to sublicense the technology for research purposes."⁷ See Ex. 6 to Mot. to Dismiss.

Open argues that Sigma's veto power over additional licenses to third parties is essentially meaningless because, according to Section 2.3, such consent may not be "unreasonably withheld" by Sigma. This section further specifies, however, that it "shall not be unreasonable for Sigma to withhold consent" for any products that it sells or intends to sell in the future. One of Sigma's significant exclusive rights is its ability under Section 4.1 of the License Agreement to grant sublicenses. See Evident Corp. v. Church & Dwight Co., Inc., 399 F.3d 1310, 1313 (Fed. Cir. 2005) ("significant rights" in exclusive license agreement included right to grant sublicenses); Intellectual Property Dev., 248 F.3d at 1338 (same). If Sigma expressly *consents* to a third-party license under Section 3.3, then it is essentially granting a sublicense and there is no conflict with its exclusive rights. If Sigma withdraws consent, then Oxford might sue Sigma for breach of contract, but it cannot unilaterally grant the third-party license.

The record shows that Oxford and Sigma have granted one such joint license agreement for a research lab, which was expressly styled as a sublicense of Sigma's exclusive rights. Nolan Decl., ¶¶ 29-31. This is consistent with Sigma's status as the exclusive licensee. The plaintiffs state that the purpose of the clause concerning the grant of additional licenses was to allow Sigma and Oxford to grant an accommodation to a research lab which needed an experimental or specialized product that Sigma did not itself sell or want to sell. In those circumstances, Sigma and Oxford could jointly

⁷Sigma has the right to grant sublicenses under the License Agreement without obtaining the consent or approval of Oxford. Sigma is obligated to advise Oxford of executed sublicense agreements, provide Oxford with a summary of key financial terms, and state in all sublicenses that Oxford is a third-party beneficiary thereof. See License Agreement, § 4.1.

agree to grant the research lab a narrow license to manufacture the product itself for its own internal research, but not for sale to third parties. See Yousaf Decl., ¶¶ 7-10; Nolan Decl., ¶¶ 25-28.

In sum, the plaintiffs entered into a detailed License Agreement in which Oxford has granted Sigma the exclusive world-wide rights within a defined field, *i.e.*, manufacturing and selling the patented products to researchers, and has simultaneously promised not to grant any additional licenses that compete with those rights. This constitutes an exclusive license. See Depuy Spine, 469 F.3d at 1025 (license is exclusive “if the patentee has promised, expressly or impliedly, that ‘others shall be excluded from practicing the invention’ within the field covered by the license.”)

Other sections of the License Agreement confirm the exclusive nature of Sigma’s license. In Sections 10.1 and 10.2, for example, the parties agree to coordinate litigation efforts against infringers. Although Oxford is granted the first right to initiate infringement litigation, these sections provide that Sigma may bring suit on its own and Oxford agrees to join as a party plaintiff in any suit initiated by Sigma, upon request. These sections are consistent with the parties’ understanding that Sigma is an exclusive licensee with co-plaintiff standing, rather than merely a bare licensee with no standing. See Abbott Labs., 47 F.3d at 1129, 1132 (holding that similar coordination-of-litigation clause was consistent with being an exclusive licensee).⁸

In Section 2.4 of the License Agreement, Sigma has a right of first refusal for a license for certain other patented products. In Section 2.6, the parties agree to form a Joint Technology

⁸The Court recognizes that although express covenants may “regulate the duties between the licensor and licensee to implement the rights of the parties,” “a contract cannot change the statutory requirement for suit to be brought by the ‘patentee.’” Ortho Pharm. Corp. v. Genetics Institute, Inc., 52 F.3d 1026, 1034 (Fed. Cir. 1995) (citing Independent Wireless, 269 U.S. at 469). “[A] right to sue clause cannot negate the requirement that, for co-plaintiff standing, a licensee must have beneficial ownership of some of the patentee’s proprietary rights.” Ortho Pharm., 52 F.3d at 1034. As discussed above, the Court concludes that Sigma is an exclusive licensee with co-plaintiff standing.

Committee to evaluate other potential licensees and to coordinate patent prosecution efforts. In Section 2.7, Sigma agrees to make a substantial capital investment in Oxford in exchange for these exclusive rights (disclosed in the press release as being a \$5 million investment). See Ex. 6 to Mot. to Dismiss. Finally, Section 13.2 grants Sigma the right to transfer or assign the License Agreement at any time without Oxford's consent.⁹ This right of transfer or assignment is an "important indicia of a true ownership interest in the patent." See Propat, 473 F.3d at 1194. None of these provisions is consistent with a bare, nonexclusive license.

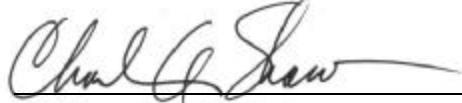
Conclusion.

For the foregoing reasons, the Court concludes that plaintiff Sigma holds an exclusive license from Oxford to make and sell the Licensed Products within the research market, and therefore was able to bring this suit by itself and later join the patentee, Oxford, as a co-party. See Evident Corp., 399 F.3d at 1312-14; Intellectual Property Dev., 248 F.3d at 1348. Defendant Open Biosystems, Inc.'s motion for dismiss for lack of standing should therefore be denied.

⁹ Sigma would require Oxford's prior written approval to transfer or assign the License Agreement only if Sigma had not paid all license fees. Even in that instance, Oxford's approval is not to be unreasonably withheld, conditioned or delayed. See License Agreement, § 13.2.

Accordingly,

IT IS HEREBY ORDERED that defendant Open Biosystems, Inc.'s motion for dismiss for lack of standing is **DENIED**. [Doc. 41]



CHARLES A. SHAW
UNITED STATES DISTRICT JUDGE

Dated this 3rd day of July, 2007.